E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2016-0732; FRL-9942-01-OCSPP]

Perchloroethylene (PCE); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and seeking public comment on a draft revision to the risk determination for the Perchloroethylene (PCE) risk evaluation issued under TSCA. The draft revision to the PCE risk determination reflects the announced policy changes to ensure the public is protected from unreasonable risks from chemicals in a way that is supported by science and the law. In this draft revision to the risk determination EPA finds that PCE, as a whole chemical substance, presents an unreasonable risk of injury to health when evaluated under its conditions of use. In addition, this revised risk determination does not reflect an assumption that all workers always appropriately wear personal protective equipment (PPE). EPA understands that there could be occupational safety protections in place at workplace locations; however, not assuming use of PPE reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, or their employers are out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being "outdated and inadequate for ensuring protection of worker health." . This revision, when final, would supersede the condition of use-specific no unreasonable risk determinations in the December 2020 PCE risk evaluation (and withdraw the associated order) and would make a revised determination of unreasonable risk for PCE as a whole chemical substance.

DATES: Comments must be received on or before **[INSERT DATE 30 DAYS AFTER**

PUBLICATION IN THE Federal Register].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-EPA-HQ-OPPT-2016-0732, using the *Federal eRulemaking Portal* at *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Kelly Summers, Office of Pollution Prevention and Toxics (7404M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-2201; email address: *summers.kelly@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of interest to those involved in the manufacture, processing, distribution, use, disposal, and/or the assessment of risks involving chemical substances and mixtures. You may be potentially affected by this action if you manufacture (defined under TSCA to include import), process (including recycling), distribute in commerce, use or dispose of PCE, including PCE in products. Since other entities may also be interested in this draft revision to the risk determination, EPA has not attempted to describe all the specific entities that may be affected by this action.

B. What is EPA's authority for taking this action?

TSCA section 6, 15 U.S.C. 2605, requires EPA to conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation (PESS) identified as relevant to the risk evaluation by the Administrator, under the conditions of use. 15 U.S.C. 2605(b)(4)(A). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that provide instruction on chemical substances that must undergo evaluation, the minimum components of a TSCA risk evaluation, and the timelines for public comment and completion of the risk evaluation. TSCA also requires that EPA operate in a manner that is consistent with the best available science, make decisions based on the weight of the scientific evidence, and consider reasonably available information. 15 U.S.C. 2625(h), (i), and (k).

The statute identifies the minimum components for all chemical substance risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation to be conducted, which includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider. 15 U.S.C. 2605(b)(4)(D). The statute further provides that each risk evaluation must also: (1) Integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on relevant potentially exposed or susceptible subpopulations; (2) Describe whether aggregate or sentinel exposures were considered and the basis for that consideration; (3) Take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use; and (4) Describe the weight of the scientific evidence for the identified hazards and exposures. 15 U.S.C. 2605(b)(4)(F)(i) through (ii) and (iv) through (v). Each risk evaluation must not consider costs or other non-risk factors. 15 U.S.C. 2605(b)(4)(F)(iii).

EPA has inherent authority to reconsider previous decisions and to revise, replace, or repeal a decision to the extent permitted by law and supported by reasoned explanation. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). Pursuant to such authority, EPA is reconsidering the risk determinations in the December 2020 PCE Risk Evaluation.

C. What action is EPA taking?

EPA is announcing the availability of and seeking public comment on a draft revision to the risk determination for the risk evaluation for PCE under TSCA, which was initially published in December 2020 (Ref. 1). EPA is specifically seeking public comment on the draft revision to the risk determination for the risk evaluation where the agency intends to determine that PCE, as a whole chemical, presents an unreasonable risk of injury to health when evaluated under its conditions of use. The Agency's risk determination for PCE is better characterized as a whole chemical risk determination rather than condition-of-use-specific risk determinations. Accordingly, EPA would revise and replace section 5 of the risk evaluation for PCE where the findings of unreasonable risk to health were previously made for the individual conditions of use evaluated. EPA would also withdraw the order issued previously for two conditions of use previously determined not to present unreasonable risk.

This revision would be consistent with EPA's plans to revise specific aspects of the first ten TSCA chemical risk evaluations in order to ensure that the risk evaluations better align with TSCA's objective of protecting health and the environment. Under the draft revision, removing the assumption that workers always and appropriately wear PPE (see Unit II.C.) in making the whole chemical risk determination for PCE would mean that: one condition of use in addition to the original 59 conditions of use would drive the unreasonable risk for PCE; an additional route of exposure (i.e., inhalation) would also be identified as driving the unreasonable risk to workers in many of those 59 conditions of use; and additional risks for acute non-cancer effects and cancer from inhalation and dermal exposures would also drive the unreasonable risk in many of

those 59 conditions of use (where previously those conditions of use were identified as presenting unreasonable risk only for chronic non-cancer effects or for chronic non-cancer effects and cancer). Overall, 60 conditions of use out of 61 EPA evaluated would drive the PCE whole chemical unreasonable risk determination due to risks identified for human health. The full list of the conditions of use evaluated for the PCE TSCA risk evaluation is in Tables 4-125 and 4-126 of the risk evaluation (Ref. 2).

D. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/comments.html*.

II. Background

A. Why is EPA re-issuing the risk determination for the PCE risk evaluation conducted under TSCA?

In 2016, as directed by TSCA section 6(b)(2)(A), EPA chose the first ten chemical substances to undergo risk evaluations under the amended TSCA. These chemical substances are asbestos, 1-bromopropane, carbon tetrachloride, C.I. Pigment Violet (PV 29), cyclic aliphatic bromide cluster (HBCD), 1,4-dioxane, methylene chloride, n-methylpyrrolidone (NMP), perchloroethylene (PCE), and trichloroethylene (TCE).

From June 2020 to January 2021, EPA published risk evaluations on the first ten

chemical substances, including for PCE in December 2020. The risk evaluations included individual unreasonable risk determinations for each condition of use evaluated. EPA issued determinations that particular conditions of use did not present an unreasonable risk by order under TSCA section 6(i)(1).

In accordance with Executive Order 13990 (Ref. 3) and other Administration priorities (Refs. 4, 5, and 6), EPA reviewed the risk evaluations for the first ten chemical substances, including PCE, to ensure that they meet the requirements of TSCA, including conducting decision making in a manner that is consistent with the best available science.

As a result of this review, EPA announced plans to revise specific aspects of the first ten risk evaluations in order to ensure that the risk evaluations appropriately identify unreasonable risks and thereby help ensure the protection of human health and the environment (Ref. 7). To that end, EPA is reconsidering two key aspects of the risk determinations for PCE published in December 2020. First, following a review of specific aspects of the December 2020 PCE risk evaluation, EPA proposes that making an unreasonable risk determination for PCE as a whole chemical substance, rather than making unreasonable risk determinations separately on each individual condition of use evaluated in the risk evaluation, is the most appropriate approach to PCE under the statute and implementing regulations. Second, EPA proposes that the risk determination should be explicit that it does not rely on assumptions regarding the use of personal protective equipment (PPE) in making the unreasonable risk determination under TSCA section 6, even though some facilities might be using PPE as one means to reduce workers' exposures; rather, the use of PPE would be considered during risk management as appropriate.

Separately, EPA is conducting a screening approach to assess potential risks from the air and water pathways for several of the first 10 chemicals, including this chemical. For PCE the exposure pathways that were or could be regulated under another EPA administered statute were excluded from the final risk evaluation (see section 1.4.2 of the December 2020 PCE risk evaluation). This resulted in the ambient air and ambient water pathways for PCE not being

assessed. The goal of the recently-developed screening approach is to remedy this exclusion and to identify if there are risks that were unaccounted for in the PCE risk evaluation. While this analysis is underway, EPA is not incorporating the screening-level approach into this draft revised unreasonable risk determination. If the results suggest there is additional risk, EPA will determine if the risk management approaches being contemplated for PCE will protect against these risks or if the risk evaluation will need to be formally supplemented or revised.

This action pertains only to the risk determination for PCE. While EPA intends to consider and may take additional similar actions on other of the first ten chemicals, EPA is taking a chemical-specific approach to reviewing the risk evaluations and is incorporating new policy direction in a surgical manner, while being mindful of the Congressional direction on the need to complete risk evaluations and move toward any associated risk management activities in accordance with statutory deadlines.

B. What is a whole chemical view of the unreasonable risk determination for the PCE risk evaluation?

TSCA section 6 repeatedly refers to determining whether a chemical *substance* presents unreasonable risk under its conditions of use. Stakeholders have disagreed over whether a chemical substance should receive: A single determination that is comprehensive for the chemical substance after considering the conditions of use, referred to as a whole-chemical determination; or multiple determinations, each of which is specific to a condition of use, referred to as condition-of-use-specific determinations.

The proposed risk evaluation procedural rule was premised on the whole chemical approach to making an unreasonable risk determination (Ref. 8). In that proposed rule, EPA acknowledged a lack of specificity in statutory text that might lead to different views about whether the statute compelled EPA's risk evaluations to address all conditions of use of a chemical substance or whether EPA had discretion to evaluate some subset of conditions of use (i.e., to scope out some manufacturing, processing, distribution in commerce, use, or disposal

activities), but also stated that "EPA believes the word 'the' [in TSCA section 6(b)(4)(A)] is best interpreted as calling for evaluation that considers all conditions of use." (Ref. 8).

The proposed rule, however, was unambiguous on the point that an unreasonable risk determination would be for the chemical substance as a whole, even if based on a subset of uses. (See Ref. 8 at pgs. 7565-66: "TSCA section 6(b)(4)(A) specifies that a risk evaluation must determine whether 'a chemical substance' presents an unreasonable risk of injury to health or the environment 'under the conditions of use.' The evaluation is on the chemical substance—not individual conditions of use—and it must be based on 'the conditions of use.' In this context, EPA believes the word 'the' is best interpreted as calling for evaluation that considers all conditions of use."). In the proposed regulatory text, EPA proposed to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use (Ref. 8 at pg. 7480).

The final risk evaluation procedural rule (Ref. 9) stated: "As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of uses [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents." (See also 40 CFR 702.47). For the unreasonable risk determinations in the first ten risk evaluations, EPA applied this provision by making individual risk determinations for each condition of use evaluated in each risk evaluation (i.e., the condition-of-use-specific approach to risk determinations). That approach was based on one particular passage in the preamble to the final risk evaluation procedural rule, which stated that EPA will make individual risk determinations for all conditions of use identified in the scope. (Ref. 9 at pg. 33744).

In contrast to this portion of the preamble of the final risk evaluation procedural rule, the regulatory text itself and other statements in the preamble reference a risk determination *for the chemical substance* under its conditions of use, rather than separate risk determinations for each of the conditions of use of a chemical substance. In the key regulatory provision excerpted earlier

from 40 CFR 702.47, the text explains that "[a]s part of the risk evaluation, EPA will determine whether *the chemical substance* presents an unreasonable risk of injury to health or the environment under each condition of uses [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents" (Ref. 9, emphasis added). Other language reiterates this perspective. For example, 40 CFR 702.31(a) states that the purpose of the rule is to establish the EPA process for conducting a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment as required under TSCA section 6(b)(4)(B). Likewise, there are recurring references to whether the chemical substance presents an unreasonable risk in 40 CFR 702.41(a). See, for example, 40 CFR 702.41(a)(6), which explains that the extent to which EPA will refine its evaluations for one or more condition of use in any risk evaluation will vary as necessary to determine whether a chemical substance presents an unreasonable risk. Notwithstanding the one preambular statement about condition-of-use-specific risk determinations, the preamble to the final rule also contains support for a risk determination on the chemical substance as a whole. In discussing the identification of the conditions of use of a chemical substance, the preamble notes that this task inevitably involves the exercise of discretion on EPA's part, and "as EPA interprets the statute, the Agency is to exercise that discretion consistent with the objective of conducting a technically sound, manageable evaluation to determine whether a chemical substance—not just individual uses or activities—presents an unreasonable risk." (Ref. 8 at pg. 33729).

Therefore, notwithstanding EPA's choice to issue condition-of-use-specific risk determinations to date, EPA interprets its risk evaluation regulation to also allow the Agency to issue whole-chemical risk determinations. Either approach is permissible under the regulation. A panel of the Ninth Circuit Court of Appeals also recognized the ambiguity of the regulation on this point. *Safer Chemicals v. EPA, 943 F.3d 397, 413* (9th Cir. 2019) (holding a challenge about "use-by-use risk evaluations [was] not justiciable because it is not clear, due to the ambiguous text of the Risk Evaluation Rule, whether the Agency will actually conduct risk evaluations in

the manner Petitioners fear").

EPA plans to consider the appropriate approach for each chemical substance risk evaluation on a case-by-case basis, taking into account considerations relevant to the specific chemical substance in light of the Agency's obligations under TSCA. The Agency expects that this case-by-case approach will provide greater flexibility in the Agency's ability to evaluate and manage unreasonable risk from individual chemical substances. EPA believes this is a reasonable approach under TSCA and the Agency's implementing regulations.

With regard to the specific circumstances of PCE, as further explained in this notice, EPA proposes that a whole chemical approach is appropriate for PCE in order to protect health and the environment. The whole chemical approach is appropriate for PCE because there are benchmark exceedances for multiple conditions of use (spanning across most aspects of the chemical lifecycle–from manufacturing (including import), processing, industrial and commercial use, consumer use, and disposal) for health of workers, occupational non-users, consumers, and bystanders and the irreversible health effects (specifically neurotoxicity and cancer) associated with PCE exposures. Because these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, a substantial amount of the conditions of use drive the unreasonable risk; therefore, it is appropriate for the Agency to make a determination for PCE that the whole chemical presents an unreasonable risk.

As explained later in this document, the revisions to the unreasonable risk determination (section 5 of the risk evaluation) would be based on the existing risk characterization section of the risk evaluation (section 4 of the risk evaluation) and would not involve additional technical or scientific analysis. The discussion of the issues presented in this **Federal Register** notice and in the accompanying draft revision to the risk determination would supersede any conflicting statements in the prior PCE risk evaluation and the response to comments document (Ref. 10). With respect to the PCE risk evaluation, EPA intends to change the risk determination to a whole chemical approach without considering the use of PPE and does not intend to amend, nor does a

whole chemical approach require amending, the underlying scientific analysis of the risk evaluation in the risk characterization section of the risk evaluation. EPA views the peer reviewed hazard and exposure assessments and associated risk characterization as robust and upholding the standards of best available science and weight of the scientific evidence per TSCA sections 26(h) and (i).

EPA is announcing the availability of and seeking public comment on the draft superseding unreasonable risk determination for PCE, including a description of the risks driving the unreasonable risk determination under the conditions of use for the chemical substance as a whole. For purposes of TSCA section 6(i), EPA is making a draft risk determination on PCE as a whole chemical. Under the proposed revised approach, the "whole chemical" risk determination for PCE would supersede the no unreasonable risk determinations (and withdraw the associated order) for PCE that were premised on a condition-of-use-specific approach to determining unreasonable risk. When finalized, EPA's revised unreasonable risk determination would also contain an order withdrawing the TSCA section 6(i)(1) order in section 5.4.1 of the December 2020 PCE risk evaluation.

C. What revision does EPA propose about the use of PPE for the PCE risk evaluation?

In the risk evaluations for the first ten chemical substances, as part of the unreasonable risk determination, EPA assumed for several conditions of use that all workers were provided and always used PPE in a manner that achieves the stated assigned protection factor (APF) for respiratory protection, or used impervious gloves for dermal protection. In support of this assumption, EPA considered reasonably available information such as public comments indicating that some employers, particularly in the industrial setting, provide PPE to their employees and follow established worker protection standards (e.g., Occupational Safety and Health Administration (OSHA) requirements for protection of workers).

For the December 2020 PCE risk evaluation, EPA assumed based on reasonably available information that workers use PPE – specifically respirators with an APF ranging from

25 to 50 and gloves with PF 10 or 20 – for 26 occupational conditions of use. However, in the December 2020 risk evaluation, EPA determined that there is unreasonable risk for 25 of those 26 occupational conditions of use even with assumed PPE.

EPA is revising the assumption for PCE that workers always or properly use PPE, although it does not question the public comments received regarding the occupational safety practices often followed by industry respondents. When characterizing the risk to human health from occupational exposures during risk evaluation under TSCA, EPA believes it is appropriate to evaluate the levels of risk present in baseline scenarios where PPE is not assumed to be used by workers. This approach of not assuming PPE use by workers considers the risk to potentially exposed or susceptible subpopulations (workers and occupational non-users) who may not be covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan. It should be noted that, in some cases, baseline conditions may reflect certain mitigation measures, such as engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in place.

In addition, EPA believes it is appropriate to evaluate the levels of risk present in scenarios considering applicable OSHA requirements (e.g., chemical-specific permissible exposure limits (PELs) and/or chemical-specific PELs with additional substance-specific standards) as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency. Consistent with this approach, the December 2020 PCE risk evaluation characterized risk to workers both with and without the use of PPE. By characterizing risks using scenarios that reflect different levels of mitigation, EPA risk evaluations can help inform potential risk management actions by providing information that could be used during risk management to tailor risk mitigation appropriately to address any unreasonable risk identified, or to ensure that applicable OSHA requirements or industry or sector best practices that address the unreasonable risk are required for all potentially exposed or susceptible subpopulations (including self-employed individuals and public sector workers who

are not covered by an OSHA State Plan).

When undertaking unreasonable risk determinations as part of TSCA risk evaluations, however, EPA does not believe it is appropriate to assume as a general matter that an applicable OSHA requirement or industry practices related to PPE use is consistently and always properly applied. Mitigation scenarios included in the EPA risk evaluation (e.g., scenarios considering use of various PPE) likely represent what is happening already in some facilities. However, the Agency cannot assume that all facilities have adopted these practices for the purposes of making the TSCA risk determination.

Therefore, EPA proposes to make a determination of unreasonable risk for PCE from a baseline scenario that does not assume compliance with OSHA standards, including any applicable exposure limits or requirements for use of respiratory protection or other PPE. Making unreasonable risk determinations based on the baseline scenario should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location, or that there is widespread non-compliance with applicable OSHA standards. Rather, it reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan, or because their employer is out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being "outdated and inadequate for ensuring protection of worker health," (Ref. 11) or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements.

In accordance with this approach, EPA is proposing the draft revision to the PCE risk determination without relying on assumptions regarding the occupational use of PPE in making the unreasonable risk determination under TSCA section 6; rather, information on the use of PPE as a means of mitigating risk (including information received from industry respondents about occupational safety practices in use) would be considered during the risk management phase as

appropriate. This would represent a change from the approach taken in the 2020 risk evaluation for PCE and EPA invites comments on this draft change to the PCE risk determination. As a general matter, when undertaking risk management actions, EPA intends to strive for consistency with applicable OSHA requirements and industry best practices, including appropriate application of the hierarchy of controls, when those measures would address an identified unreasonable risk, including unreasonable risk to potentially exposed or susceptible subpopulations. Consistent with TSCA section 9(d), EPA will consult and coordinate TSCA activities with OSHA and other relevant Federal agencies for the purpose of achieving the maximum applicability of TSCA while avoiding the imposition of duplicative requirements. Informed by the mitigation scenarios and information gathered during the risk evaluation and risk management process, the Agency might propose rules that require risk management practices that may be already common practice in many or most facilities. Adopting clear, comprehensive regulatory standards will foster compliance across all facilities (ensuring a level playing field) and assure protections for all affected workers, especially in cases where current OSHA standards may not apply or be sufficient to address the unreasonable risk.

Removing the assumption that workers always and appropriately wear PPE in making the whole chemical risk determination for PCE would mean that: one condition of use in addition to the original 59 conditions of use would drive the unreasonable risk for PCE; an additional route of exposure (i.e., inhalation) would also be identified as driving the unreasonable risk to workers in many of those 59 conditions of use; and additional risks for acute non-cancer effects and cancer from inhalation and dermal exposures would also drive the unreasonable risk in many of those 59 conditions of use (where previously those conditions of use were identified as presenting unreasonable risk only for chronic non-cancer effects or for chronic non-cancer effects and cancer). The draft revision to the risk determination would clarify that EPA does not rely on the assumed use of PPE when making the risk determination for the whole substance. EPA is requesting comment on this potential change.

D. What is PCE?

PCE is a colorless liquid and a volatile organic compound that is manufactured (including imported), processed, distributed, used, and disposed of as part of industrial, commercial, and consumer conditions of use. PCE has a wide range of uses, including production of fluorinated compounds and as a solvent in dry cleaning and vapor degreasing. A variety of consumer and commercial products use PCE, such as adhesives (arts and crafts, as well as light repairs), aerosol degreasers, brake cleaners, aerosol lubricants, sealants, stone polish, stainless steel polish, and wipe cleaners. The total aggregate production volume reported for PCE under the Chemical Data Reporting rule ranged from 324 million to 388 million pounds between 2012 and 2015.

E. What conclusions did EPA reach about the risks of PCE in the 2020 TSCA risk evaluation and what conclusions is EPA proposing to reach based on the whole chemical approach and not assuming the use of PPE?

In the 2020 risk evaluation, EPA determined that PCE presents an unreasonable risk to health under the following conditions of use:

- Manufacturing (domestic manufacture);
- Manufacturing (import);
- Processing as a reactant/intermediate;
- Processing into formulation, mixture or reaction product for cleaning and degreasing products;
- Processing into formulation, mixture or reaction product for adhesive and sealant products;
- Processing into formulation, mixture or reaction product for paint and coating products;
- Processing into formulation, mixture or reaction product for other chemical products and preparations;
- Processing by repackaging;
- Recycling;

• Industrial and commercial use as solvent for open-top batch vapor degreasing;

• Industrial and commercial use as solvent for closed-loop batch vapor degreasing;

• Industrial and commercial use as solvent for in-line conveyorized vapor degreasing;

• Industrial and commercial use as solvent for in-line web cleaner vapor degreasing;

• Industrial and commercial use as solvent for cold cleaning;

• Industrial and commercial use as solvent for aerosol spray degreaser/cleaner;

• Industrial and commercial use as a solvent for aerosol lubricants;

• Industrial and commercial use in solvent-based adhesives and sealants;

• Industrial and commercial use in solvent-based paints and coatings;

• Industrial and commercial use in maskants for chemical milling;

• Industrial and commercial use as a processing aid in pesticide, fertilizer and other agricultural chemical manufacturing;

• Industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing;

• Industrial and commercial use in wipe cleaning;

• Industrial and commercial use in other spot cleaning and spot removers, including carpet cleaning;

• Industrial and commercial use in mold release;

• Industrial and commercial use in dry cleaning and spot cleaning post-2006 dry cleaning;

• Industrial and commercial use in dry cleaning and spot cleaning $4^{th}/5^{th}$ gen only dry cleaning;

• Industrial and commercial use in automotive care products (e.g., engine degreaser and brake cleaner);

• Industrial and commercial use in non-aerosol cleaner;

• Industrial and commercial use in metal (e.g., stainless steel) and stone polishes;

• Industrial and commercial use in laboratory chemicals;

• Industrial and commercial use in welding;

• Industrial and commercial use in other textile processing;

• Industrial and commercial use in wood furniture manufacturing;

• Industrial and commercial use in foundry applications;

• Industrial and commercial use in specialty Department of Defense uses (oil analysis and water pipe repair);

• Commercial use in inks and ink removal products (based on printing);

• Commercial use in inks and ink removal products (based on photocopying);

• Commercial use for photographic film;

• Commercial use in mold cleaning, release and protectant products;

• Consumer use in cleaners and degreasers (other);

• Consumer use as a dry cleaning solvent;

• Consumer use in automotive care products (brake cleaner);

• Consumer use in automotive care products (parts cleaner);

• Consumer use in aerosol cleaner (vandalism mark and stain remover);

• Consumer use in non-aerosol cleaner (e.g., marble and stone polish);

• Consumer use in lubricants and greases (cutting fluid);

• Consumer use in lubricants and greases (lubricants and penetrating oils);

• Consumer use in adhesives for arts and crafts (including industrial adhesive, arts and crafts adhesive, gun ammunition sealant);

• Consumer use in adhesives for arts and crafts (livestock grooming adhesive);

• Consumer use in adhesives for arts and crafts (column adhesive, caulk and sealant);

• Consumer use in solvent-based paints and coatings (outdoor water shield (liquid));

• Consumer use in solvent-based paints and coatings (coatings and primers (aerosol));

• Consumer use in solvent-based paints and coatings (rust primer and sealant (liquid));

• Consumer use in solvent-based paints and coatings (metallic overglaze);

• Consumer use in metal (e.g., stainless steel) and stone polishes;

• Consumer use in inks and ink removal products;

• Consumer use in welding;

• Consumer use in mold cleaning, release and protectant products; and

• Disposal.

Under the proposed whole chemical approach to the PCE risk determination, the unreasonable risk from PCE would continue to be driven by risk from those same conditions of use. In addition, by removing the assumption of PPE use in making the whole chemical risk determination for PCE, one condition of use in addition to the original 59 conditions of use would drive the unreasonable risk: industrial and commercial use as a solvent for penetrating lubricants and cutting tool coolants. Overall, 60 conditions of use out of the 61 EPA evaluated would drive the PCE whole chemical unreasonable risk determination.

III. Revision of the December 2020 Risk Evaluation

A. Why is EPA proposing to revise the risk determination for the PCE risk evaluation?

EPA is proposing to revise the risk determination for the PCE risk evaluation pursuant to TSCA section 6(b) and consistent with Executive Order 13990, ("Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis") and other Administration priorities (Refs. 3, 4, and 6). EPA is revising specific aspects of the first ten TSCA existing chemical risk evaluations in order to ensure that the risk evaluations better align with TSCA's objective of protecting health and the environment. For the PCE risk evaluation, this includes the draft revision: 1) Making the risk determination in this instance based on the whole chemical substance instead of by individual conditions of use, and 2) Emphasizing that EPA does not rely on the assumed use of PPE when making the risk determination.

B. What are the draft revisions?

EPA is releasing a draft revision of the risk determination for the PCE risk evaluation pursuant to TSCA section 6(b). Under the revised determination, EPA preliminarily concludes

that PCE, as evaluated in the risk evaluation as a whole, presents an unreasonable risk of injury to health under its conditions of use. This revision would replace the previous unreasonable risk determinations made for PCE by individual conditions of use, supersede the determinations (and withdraw the associated order) of no unreasonable risk for the conditions of use identified in the TSCA section 6(i)(1) no unreasonable risk order, and clarify the lack of reliance on assumed use of PPE as part of the risk determination.

These draft revisions do not alter any of the underlying technical or scientific information that informs the risk characterization, and as such the hazard, exposure, and risk characterization sections are not changed except to the extent that statements about PPE assumptions in section 2.4.1.4 (Consideration of Engineering Controls and PPE) and section 4.2.2.2 (Occupational Inhalation Exposure Summary and PPE Use Determinations by OES) of the PCE risk evaluation would be superseded. The discussion of the issues in this notice and in the accompanying draft revision to the risk determination would supersede any conflicting statements in the prior executive summary, section 2.4.1.4 and section 4.2.2.2 from the PCE risk evaluation and the response to comments document (Refs. 2 and 10). Additional policy changes to other chemical risk evaluations, including any consideration of potentially exposed or susceptible subpopulations and/or inclusion of additional exposure pathways, are not necessarily reflected in these draft revisions to the risk determination.

C. Will the draft revised risk determination be peer reviewed?

The risk determination (section 5 in the December 2020 risk evaluation) was not part of the scope of the peer review of the PCE risk evaluation by the Science Advisory Committee on Chemicals (SACC). Thus, consistent with that approach, EPA does not intend to conduct peer review of the draft revised unreasonable risk determination for the PCE risk evaluation because no technical or scientific changes will be made to the hazard or exposure assessments or the risk characterization.

D. What are the next steps for finalizing revisions to the risk determination?

EPA will review and consider public comment received on the draft revised risk determination for the PCE risk evaluation and, after considering those public comments, issue the revised final PCE risk determination. If finalized as drafted, EPA would also issue a new order to withdraw the TSCA section 6(i)(1) no unreasonable risk order issued in Section 5.4.1 of the 2020 PCE risk evaluation. This final revised risk determination would supersede the December 2020 risk determinations of no unreasonable risk. Consistent with the statutory requirements of TSCA section 6(a), the Agency would then propose risk management actions to address the unreasonable risk determined in the PCE risk evaluation.

IV. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

1. EPA Draft Revised Unreasonable Risk Determination for Perchloroethylene, Section 5, June 2022.

2. EPA. Risk Evaluation for Perchloroethylene. EPA Document #740-R1-8011. December 2020. *https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0502-0058.*

3. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. *Federal Register.* 86 FR 7037, January 25, 2021.

4. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. *Federal Register.* 86 FR 7009, January 25, 2021.

5. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. *Federal Register.* 86 FR 7619, February 1, 2021.

6. Presidential Memorandum. Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. *Federal Register.* 86 FR 8845, February 10, 2021.

7. EPA Press Release. EPA Announces Path Forward for TSCA Chemical Risk Evaluations. June 2021. https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations.

8. EPA. Proposed Rule; Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act. *Federal Register.* 82 FR 7562, January 19, 2017 (FRL-9957-75).

9. EPA. Final Rule; Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act. *Federal Register.* 82 FR 33726, July 20, 2017 (FRL-9964-38).

10. EPA. Summary of External Peer Review and Public Comments and Disposition for Perchloroethylene (PCE). December 2020. https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0502-0059.

11. Occupational Safety and Health Administration. Permissible Exposure Limits – Annotated Tables. Accessed June 13, 2022. *https://www.osha.gov/annotated-pels.*

Authority: 15 U.S.C. 2601 *et seq.*

Dated: June 27, 2022.

Michal Freedhoff,

Assistant Administrator,

Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2022-14016 Filed: 6/29/2022 8:45 am; Publication Date: 6/30/2022]